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Via ECF and Federal Express

The Honorable F. Dennis Saylor, IV
United States District Court
Donohue Federal Building
595 Main Street
Worcester, MA 01608

Re: *Abbott GmbH & Co., KG et al. v. Centocor Ortho Biotech, Inc. et al.*, C.A. No. 4:09-cv-11340

Dear Judge Saylor:

This letter is submitted on behalf of Centocor to advise the Court of the Federal Circuit's recent decision on willful infringement, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc.*, No. 2010-1510 (Fed. Cir. June 14, 2011) (Attachment A). Because of this decision, Centocor submits that Abbott's willful infringement claim cannot be tried to the jury with the remaining liability and damages issues.

Centocor submits this letter to explain the issues raised by the *Bard* case and to present a proposal for disposing of (by summary judgment) or trying Abbott's willful infringement claim, so that the parties might discuss them during the telephonic status conference scheduled for July 18 at 10:00 AM.

I. The Law of Willful Infringement and the *Bard* Decision

Abbott alleges that Centocor infringes claims of two patents, and that its infringement is willful. A finding of willful infringement allows, in the Court's discretion, an award of enhanced damages under 35 U.S.C. §284.

In *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc) (Attachment B), the Federal Circuit created a two-pronged test for establishing willful infringement. Under the first prong, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. *Id.* at 1371. The state of mind of the accused infringer is not relevant to this objective inquiry. *Id.* Following *Seagate*, the Federal Circuit established the rule that generally the "'objective'

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prong of *Seagate* tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement.” *Bard*, slip op. at 4-5 (citing *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010) (Attachment C) (denial of JMOL of no willfulness reversed where defendant raised a substantial question as to the obviousness of asserted patent)); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336-1337 (Fed. Cir. 2009) (Attachment D) (holding that the district court correctly granted JMOL of no willfulness where defendant “presented a substantial question” of noninfringement under the doctrine of equivalents, even though the jury found equivalence). The objectively-defined risk prong is “determined by the record developed in the infringement proceeding.” *Seagate*, 497 F.3d at 1371.

If the patentee satisfies this threshold objective standard, the second prong of the willfulness test requires the patentee to demonstrate that “this objectively defined risk . . . was either known or so obvious that it should have been known to the accused infringer.” *Id.* It is only under this second, subjective prong of the willfulness test that the accused infringer’s state of mind becomes relevant. Evidence generally presented in connection with the subjective prong of the *Seagate* test has to do with the accused infringer’s knowledge of the asserted patent and reliance on advice of counsel with respect to the patent.

Before the *Bard* decision, the ultimate question of willfulness had been treated as a question of fact, with the two-prong test presented to the jury. But in *Bard*, the Federal Circuit recognized that the *court* is in the best position to decide the *threshold*, objective prong of the willfulness test, that is, to make the determination of the reasonableness of an accused infringer’s defenses. It held that “the objective determination of recklessness, even though predicated on underlying mixed questions of law and fact, is best decided by the judge as a question of law subject to *de novo* review.” *Bard*, slip. op. at 6-7. This recent proclamation controls how Abbott’s willful infringement claim should be tried in this case.

II. The Issue of Objective Recklessness Must Be Decided By the Court as a Threshold Question

The *Bard* decision gives little guidance to district courts as to how to sequence trial of a willfulness claim. But what is clear is that, in this case, the *Court* must make the *threshold* determination of whether Centocor’s defenses to Abbott’s infringement claims are reasonable. Per *Seagate*, that determination is to be made based on the “record developed in the infringement proceeding.” *Seagate*, 497 F.3d at 1371. That record will not be complete until trial is complete.

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For reasons explained below, Centocor contends that it is only if, and after, the Court has determined as a matter of law that Centocor has no reasonable defenses that the jury should be presented with evidence or argument on the second, subjective prong of the willfulness test.

Centocor proposes pre-trial summary judgment briefing on the objective prong, and, if necessary after the briefing, a bifurcated trial, to allow the Court to fairly consider the relevant record before making its legal determination. This proposal is the only way to comply with *Bard* and avoid jury confusion and prejudice to Centocor.

A. Centocor's Defenses Are Numerous and Varied

The "record developed in the infringement proceeding," on the basis of which the Court must make its legal determination of objective recklessness, will include numerous Centocor defenses to Abbott's infringement allegations. These defenses include defenses already presented to the Court in the context of summary judgment briefing, additional defenses that will be presented to the jury at trial, and still other defenses that have been lost to Centocor because of the Court's claim construction rulings but which, Centocor contends, were nonetheless reasonable.

Centocor moved for summary judgment on a number of its defenses, including invalidity for lack of written description, invalidity for anticipation by prior invention, and noninfringement of the "K_d" claims. In the case of each of Centocor's motions on these issues, the Court found there to be material factual disputes and denied summary judgment (D.I. 341 at 44, 49, 63, 68-69). Centocor has additional defenses which will be presented to the jury, such as nonenablement and obviousness. The Court can find that the credibility and reasonableness of any of these defenses preclude a finding of willful infringement. *DePuy*, 567 F.3d at 1337 (holding that a finding of willful infringement was precluded because "the question of equivalence was a close one" and required "an intensely factual inquiry"); *Safoco, Inc. v. Cameron Int'l Corp.*, 2009 WL 2424108, at *23 (S.D. Tex. 2009) (Attachment E) (willfulness precluded by close issue of fact relating to infringement); *ResQNet.com, Inc. v. Lansa, Inc.*, 533 F. Supp. 2d 397, 420 (S.D.N.Y. 2008) (Attachment F) (no willful infringement because defenses, though ultimately unsuccessful, were substantial and reasonable).

B. "Objective Recklessness" Should Be Found And Defined Before A Jury Is Presented With Evidence Relating to the Second, Subjective *Seagate* Prong

As the *en banc Seagate* Court held, "If this threshold objective standard is satisfied, the patentee must also demonstrate that *this* objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have

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been known to the accused infringer.” *Seagate*, 497 F.3d at 1371 (emphasis added). In other words, only if the Court determines that Centocor had no reasonable defenses, does the question of Centocor’s subjective knowledge and behavior, a fact issue for the jury, come into play.

Moreover, before the Court can instruct the jury on the subjective prong – namely, whether the objective risk was known or should have been known to Centocor – the Court has to be able to define for the jury *what* the objective risk *was*. Although Centocor contends that all of its defenses are highly reasonable, it is possible that the Court might determine that some defenses pass that test, and others do not. Or, the Court may determine that Centocor has reasonable defenses for some patent claims, but not for other patent claims. The jury cannot be asked to determine the subjective reasonableness of Centocor’s behavior in the face of an objective risk, without knowledge of what the Court deemed the objective risk to be. And it would be prejudicial to put Centocor in the position of having to present evidence of the reasonableness of its behavior in the face of an objective risk that the Court may later determine did not even exist. This would be confusing to the jury and would unfairly predispose it to believe that Centocor’s defenses were not reasonable. The Court cannot make the determination of whether there was an objective risk before it has heard all of the evidence at trial.

III. Centocor’s Proposal for Briefing and/or Trying Willfulness

In view of the *Bard* decision denominating the “objective recklessness” prong of the willfulness test as a question of law for the Court, the old way of simply trying willful infringement to the jury along with other liability issues and damages is no longer feasible, at least not in this case. Centocor submits that the Court cannot determine that Centocor has no reasonable defenses until it has heard all of the evidence at trial (some of which, such as the reasonableness of Centocor’s invalidity defense to be tried to the Court in the Section 146 Action, will have to be out of the jury’s hearing). However, since a number of Centocor’s defenses have already been briefed to the Court during summary judgment briefing (including written description, anticipation by prior invention, and noninfringement of K_d claims), Centocor proposes that the Court accept summary judgment briefing, before trial, on the objective prong. Centocor believes that the evidence already in the record on these defenses could be easily and succinctly summarized for the Court, and that it would convince the Court that, as a matter of law, Centocor has reasonable defenses to Abbott’s infringement charges. With such a finding on the threshold issue, the issue of willfulness could be put to rest before the September trial.

Were the Court to prefer not to have summary judgment briefing before trial, or were it to deny Centocor’s summary judgment motion, Centocor proposes that trial of willfulness be bifurcated from trial on the other liability and damages issues. For the reasons explained above,



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the Court would have to make its legal determination of objective recklessness based on a full record, which would be complete only after trial is complete and after Centocor has also had an opportunity, outside the hearing of the jury, to present evidence relating to the reasonableness of defenses it had based on the priority of the count in the Section 146 action, or of defenses it may elect, for other reasons, not to present to the jury. The Court has already granted Abbott's request to bifurcate discovery and determination of injunctive relief until after any determination of liability (D.I. 157 at 19:22-20:22).

Centocor had hoped to engage Abbott on these issues before making this submission to the Court, but has received no response to the proposal it made to Abbott by letter of June 29 (Attachment G). Centocor is submitting this letter in an effort to give the Court sufficient time to consider these issues prior to the July 18 status conference. We look forward to discussing this proposal at the Court's convenience and to answering any questions the Court may have.

Respectfully submitted,

A handwritten signature in cursive script that reads "Dianne Elderkin".

Dianne B. Elderkin

cc: William F. Lee (via e-mail)
Robert J. Gunther (via e-mail)